Australian Government

Department of Health

Therapeutic Goods Administration

Consultation: Proposed changes to the classification of active implantable medical devices and their accessories

March 2019

TGA Health Safety Regulation

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Introduction

The Australian Government endorsed a significant program of reform to further strengthen the regulation of medicines and medical devices in Australia. As part of the Australian Government Department of Health, the Therapeutic Goods Administration (TGA) regulates these products, and is responsible for implementing the Government's reforms.

In 2015, the Report of the *Expert Panel Review of Medicines and Medical Devices Regulation* (MMDR) made 58 recommendations for reform of the regulatory framework for medicines and medical devices in Australia. The Australian Government Response to the Review of Medicines and Medical Devices Regulation was released in September 2016. The Government accepted 56 MMDR recommendations including Recommendation Twenty[1] which addressed matters within the remit of the TGA. This Recommendation provided that the regulation of medical devices, wherever possible and appropriate, align with the European Union (EU) framework including the classification of medical devices.

Background

Medical devices are regulated in Australia having regard to the risks (to the individual or public health) considered in the context of the device's intended use. All devices carry some level of potential risk, and the TGA applies scientific and clinical expertise to ensure assessments and decisions are made based on the balance between the benefits and the risks.

The risk classifications of medical devices take into account factors such as potential harm, level of invasiveness, reliance on power, where in the human body the device is used, terms of use, the end user (consumers or a person with appropriate knowledge and expertise), etc.

The TGA periodically reviews classification rules for medical devices to ensure they continue to be appropriate. When undertaking such reviews, the TGA has regard among other things, to the international best regulatory practice and any emerging issues.

This ensures sustainability of the Australian regulatory system for medical devices, appropriateness and robustness of assessments, and timeliness of access to medical devices.

This consultation

The focus of this paper is to obtain feedback on a proposal for the classification of active implantable medical devices and reclassification of their non-implantable accessories.

The EU Regulation on medical devices (2017/745)[2] (EU MD Regulation) introduced several amendments to the classification rules effectively reclassifying some categories of medical devices to higher risk classes.

[1] Sansom L, Delaat W, Horvath J. Review of Medicines and Medical Devices Regulation: Recommendations to the Minister for Health on the Regulatory Frameworks for Medicines, Medical Devices, Complementary Medicines and Advertising of Therapeutic Goods, July 2015, p. 10.

[2] The Regulation 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

The EU MD Regulation explains that the new requirements increase the robustness of the assessment process, and that the classification rules take into account potential risks associated with the technical design and manufacture of the devices. The rules also take into account the level of invasiveness and potential toxicity of certain devices introduced into the human body as well as the place where the device performs its action in or on the human body.

The Australian Government's reforms aim to improve the scope, clarity and appropriateness and operation of regulations governing medical devices. This consultation paper considers the EU regulatory framework as an input into the review and reform of the Australian regulatory requirements for medical devices classification. While the new classification rule in the EU more appropriately reflects the intended use and the risk of medical devices, this paper considers the extent to which a similar approach will be appropriate in the Australian regulatory context, to further our aim of enhancing the smooth functioning of the medical devices market while also achieving high standards of quality, safety and performance.

Potential changes: summary

Aim

Having regard to the amendments implemented by the EU MD Regulation, in the context of the Australian regulatory requirements, consider:

- Simplifying classification rules by amending the classification of active implantable medical devices (AIMD) from Class AIMD to Class III; and
- Amending the classification rule for accessories to AIMD to expand it to any accessory.

Proposals

It is proposed that the *Therapeutic Goods (Medical Devices) Regulations 2002*, **classification rule 5.7** be amended to align with the **sixth dot point of Rules 8,** the **fourth paragraph of Rule 9** and **paragraph 3.3 of the Implementing Rules** (Annex VIII, Chapter III and II respectively) of the EU MD Regulation.

Effect

Classification of **AIMD, their accessories, active devices intended for controlling, monitoring or influencing the performance of an AIMD and software that drives or influences the use of an AIMD** will be **Class III (high risk) medical devices**.

Your feedback

Are you a consumer, industry stakeholder, healthcare provider, patient, industry representative body, consumer advocacy group or other interested party?

We seek your views on the proposed implementation measures. Your input will assist us to address any unintended consequences so as to inform the proposal and the regulatory amendment process.

On page 14 is a list of questions to help you address the proposal in your feedback.

Please refer to page 15 on How to submit your feedback to the TGA.

Please note

This consultation closes on **29 April 2019**.

Before providing feedback, it is important to read the explanatory material that follows.

Where do I find the classification and definitions related to active implantable medical devices and accessories?

EU MD Regulation

Regulation (EU) 2017/745 (the EU MD Regulation) specifies the rules that govern the classification of a medical device.

Active implantable medical devices (or ***AIMD***) are medical devices that operate on a source of electrical power, are intended to be introduced wholly or partially into the body during a procedure and are intended to remain in place after the procedure.

Historically, the EU regulated all medical devices (including AIMD but excluding *in vitro* diagnostic medical devices) under two separate legal instruments: Directive 90/385/EEC and Directive 93/42/EEC.[3] In the interest of simplification, the EU has now consolidated and provided the requirements applicable for all medical devices (including AIMD but excluding *in vitro* diagnostic medical devices) in a single legislative act (the EU MD Regulation).[4]

To align with international practices, the EU MD Regulation classifies medical devices into four (4) classes. The classification rules, which are based on the vulnerability of the human body, take into account the potential risks associated with the technical design and manufacture of the medical devices. To maintain the same level of safety as provided by Directive 90/385/EEC, the EU MD Regulation classifies AIMD in the highest risk class.[5]

Further, similar to Directive 90/385/EEC[6], the EU MD Regulation continues to classify accessories to AIMD and any active device intended to control, monitor or directly influence the performance of active implantable medical devices as high risk medical devices.

The classification of AIMD, their accessories, and other active devices used together with AIMD are detailed in the classification rules specified in the sixth dot point of Rule 8 and the fourth paragraph of Rule 9 of the EU MD Regulation. The EU MD Regulation also provides the principles for applying the classification rules and considers software that drives or influences a device as having the same classification as the device (paragraph 3.3 of the Implementing Rules).

[3] Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (OJ L 189, 20.7.1990); and Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ L 169, 12.7.1993.

[4] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, (6), p. 2

[5] OJ L 117, 5.5.2017, (58).p. 8

[6] Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (OJ L 189, 20.7.1990); and EC Medical Devices: Guidance document - Field of application of Directive 90/385/EEC on active implantable medical devices - MEDDEV 2.1/2 rev.2 (26 April 1994) http://ec.europa.eu/DocsRoom/documents/10279/attachments/1/translations

Chapter III Classification Rules[7]

Rule 8

'All implantable devices and long-term surgically invasive devices are classified as class IIb unless they:

[...] (6th dot point)

- *are active implantable devices or their accessories, in which cases they are classified as class III'*

Rule 9

[...] (4th paragraph)

'All active devices that are intended for controlling, monitoring or directly influencing the performance of active implantable devices are classified as class III.'

Chapter II Implementing Rules

3.3 Software, which drives a device or influences the use of a device, shall fall within the same class as the device.

The EU MD Regulation does not explicitly define ***active implantable medical devices*** or ***software***. However, there are definitions of ***accessory for a medical device***, ***implantable devices***, ***invasive device*** and ***active device***. The EU MD Regulation also clarifies that software is deemed to be an *active device.*[8]

The TGA is consulting on the possible alignment of these definitions (and interpretation of software) with the respective provisions in the Australian MD Regulations separately.[9,10,11]

Australia

The classification rules for medical devices in Australia are prescribed in Schedule 2 of the *Therapeutic Goods (Medical Devices) Regulations 2002* (the Australian MD Regulations).[12]

The current classification rules relevant to AIMD and medical devices used in association with AIMD are prescribed in Part 5, Schedule 2 of the Australian MD Regulations and are outlined in 'Current classification of these devices in Australia' (page 11 of this paper).

Appendix A – Classification Rules and Definitions (on page 16) has been included as a reference tool. It provides a comparison of the EU MD Regulation and Australian MD Regulations in regards to the classification rules and definitions relevant to AIMD.

[7] This rule covers multiple groups of devices, this consultation paper only provides extracts relevant to the subject of this consultation

[8] OJ L 117, 5.5.2017, Article 2(4), p.16

[9] *Consultation: Changes to a number of definitions and scope of the medical device regulatory framework in Australia* https://www.tga.gov.au/consultation/consultation-changes-number-definitions-and-scope-medical-device-regulatory-framework-australia, Appendix A, Table A2, p.15

[10] *Consultation: Potential reclassification of active medical devices for diagnosis and patient therapy* https://www.tga.gov.au/consultation/consultation-potential-reclassification-active-medical-devices-diagnosis-and-patient-therapy

[11] Consultation: Regulation of software, including Software as a Medical Device (SaMD) *http://www.tga.gov.au/consultation/consultation-regulation-software-including-software-medical-device-samd*

[12] Classification rules for IVD medical devices are prescribed in Schedule 2A; see also *Therapeutic Goods Act 1989*, s. 41DB and *Therapeutic Goods (Medical Devices) Regulations 2002*, Part 3, Div. 3.1.

Appendix A may help you in providing your feedback.

Medical devices subject to EU MD Regulation Rules 8 and 9

The **sixth dot point of Rule 8** and **fourth paragraph of Rule 9** classify AIMD, all their accessories, active devices intended for controlling, monitoring or influencing the performance of an AIMD and software that drives or influence the use of an AIMD.

What are AIMD and other devices used together with an AIMD?

Brief descriptions of some AIMD and medical devices used together with an AIMD are provided below. Further details including current and proposed classification are provided in Appendix B (on page 20).

IMPORTANT

This consultation paper is seeking feedback on the proposed reclassification of **AIMD** and their **non-implantable accessories** to **Class III**. The examples provided below cover AIMD and their accessories; and are intended to highlight the risks associated with the use of these devices.

Implantable accessories and **active devices intended to control, monitor or directly influence the performance of an AIMD** are currently classified as **Class III**, and TGA is not proposing any changes to the classification of these devices. These devices will remain as Class III.

Implantable cardiac pacemakers and accessories

Cardiac pacemakers are medical devices that generate electrical impulses to the heart and are used to treat arrhythmias including tachycardia (when the heart beats too fast), bradycardia (when the heart beats too slowly) or an irregular rhythm. During an arrhythmia, the heart may not be able to pump enough blood to the body. This can cause symptoms such as fatigue (tiredness), shortness of breath or fainting. Severe arrhythmias can damage the body's vital organs and may even cause loss of consciousness or death.

Most pacemakers consist of a pulse generator, pacemaker leads, external programmer (computer) with software and other accessories.

Further information on the pacemaker examples is included in Appendix B, Table B (Paragraph B.1) (on page 20).

Implantable cardioverter-defibrillators (ICD) and accessories

An implantable cardioverter-defibrillator (ICD) and automated implantable cardioverter defibrillator (AICD) are implantable medical devices that are able to perform cardioversion, defibrillation, and (in modern versions) pacing of the heart.

The ICD delivers an electric current (often called a counter-shock) to the heart. It is used as a treatment for life-threatening cardiac dysrhythmias, specifically ventricular fibrillation (VF) and non-perfusing ventricular tachycardia (VT). It is considered first-line treatment and prophylactic therapy for patients at risk for sudden cardiac death due to ventricular fibrillation and ventricular tachycardia.

Both ICD and AICD usually consist of defibrillators (battery powered active implantable medical devices), leads, ICD programmers and accessories.

Further information on implantable cardioverter-defibrillators is included in Appendix B, Table B (Paragraph B.2) (on page 22).

Cochlear implants

A cochlear implant (also known as a 'bionic ear') is a small electronic device that is surgically inserted into a person's inner ear (the cochlea). Cochlear implants bypass the normal acoustic hearing process by replacing it with electric hearing. The auditory nerve is directly stimulated by sound being converted to electric signals. The brain adapts to the new mode of hearing and can eventually interpret the electric signals as sound and speech.

Cochlear implants usually consist of a processing unit, the actual implant, and accessories.

Further information on cochlear implants is included in Appendix B, Table B (Paragraph B.3) (on page 23).

Why change the classification of AIMD and their accessories?

Classification of AIMD

AIMD are currently classified in the Australian MD Regulation as Class 'AIMD'. If the classification of AIMD is changed to Class III, this will harmonise the Australian MD Regulations with the EU MD Regulation and more broadly internationally.

The current conformity assessment procedures applied to AIMD in Australia are the same as for a Class III medical device; therefore there will be no change to the level of the regulatory requirements.[13]

The proposed reclassification will improve clarity and consistency in the terminology and facilitate a better functioning of the medical devices market while also achieving timely access and high standards of quality, safety and performance.

Classification of AIMD accessories (both implantable and non-implantable)

Currently, implantable accessories to AIMD are classified as Class III in the Australian MD Regulations. Non-implantable accessories to AIMD may fall under three different classification rules (Class I, Class IIa or Class III) depending on the intended purpose of the device.

*'**Accessory to a medical device**'* is a medical device intended by its manufacturer to be used together with one or several particular medical device(s) to specifically enable the medical device(s) to be used in accordance with its/their intended purpose(s) or to specifically and directly assist the medical functionality of the medical device(s) in terms of its/their intended purpose(s).[14]

[13] *Therapeutic Goods (Medical Devices) Regulations 2002*, Div.3.2 - Conformity assessment procedures, Regulation 3.6 - Class III medical devices and Class AIMD medical devices (other than medical devices used for a special purpose)
[14] OJ L 117, 5.5.2017, Article 2(2).p. 16

AIMD have high risks associated with its use due to many different factors, including the combination of implantation and the use of energy sources inside the body, seriousness of medical indications for which these devices are used, the high requirements for maintenance and calibration, etc.

Therefore, any accessory (both implantable and non-implantable) intended to be used together with an AIMD to specifically enable the AIMD to be used in accordance with its/their intended purpose(s) or to assist the functionality of the AIMD, also potentially presents a high risk if they do not perform as intended.

The proposed change to the classification of all AIMD accessories (both implantable and non-implantable) to Class III ensures that appropriate assessment is undertaken commensurate with the level of risks of the device, and it will also harmonise the Australian MD Regulations with the EU MD Regulation.

Classification of active devices intended for controlling, monitoring or directly influencing the performance of AIMD

Any active medical device intended by the manufacturer to be used to control, monitor or directly influence the performance of an AIMD is currently classified as Class III. Therefore, there will be no changes in the classification for devices from this group.

Is amending the classification of any or all of these devices in Australia to Class III appropriate?

Current classification of these devices in Australia

The classification rules that currently apply to these devices are set out in Schedule 2, Part 5 of the Australian MD Regulations as follows:

> ***Part 5—Special rules for particular kinds of medical devices***
>
> ***Rule 5.7 Active implantable medical devices***
>
> *(1) An active implantable medical device is classified as Class AIMD.*
>
> *(2) An implantable accessory to an active implantable medical device is classified as Class III.*
>
> *(3) An active medical device that is intended by the manufacturer to be used to control or monitor, or directly influence, the performance of an active implantable medical device is classified as Class III.*
>
> ***Note**: Non-implantable accessories to AIMD currently may fall under different classification rules in Schedule 2 of the Australian MD Regulations.*

Proposed amendments to the classification rules

If the proposed changes take effect, all AIMD will be classified as Class III.

This proposal will also mean that **any accessory to AIMD** (both implantable and non-implantable) will be classified as **Class III**, i.e. **non-implantable accessories will be reclassified as high-risk devices**.

There will be no changes to the classification of active devices intended for controlling, monitoring or directly influencing the performance of an AIMD, as medical devices from this category are already classified as Class III in Australia.

Effect of changes for non-implantable accessories to AIMD

Sponsors of Class III medical devices in Australia are required to include each device in the Australian Register of Therapeutic Goods (ARTG) separately, with an individual unique product identifier (UPI) to improve their traceability. Medical devices of the high risk classification require the most stringent assessment of manufacturer's quality management systems and assessment of technical documentation related to each device, rather than that of a representative device from a group of similar devices[15]. Sponsors will be required to obtain manufacturer's *conformity assessment documents*[16] and provide them to the TGA to demonstrate procedures appropriate for a Class III medical device when submitting applications for inclusion of their medical devices in the ARTG. The Class III device applications are also subject to a mandatory audit assessment by the TGA, including assessment of the clinical evidence.

Strengthened assessments are intended to drive the design and manufacture of better quality, reliable medical devices that are fit for purpose.

Proposed action

It is proposed that **Rule 5.7 (Active implantable medical devices), Schedule 2** of the *Therapeutic Goods (Medical Devices) Regulations 2002*, be amended, to align with the EU MD Regulation Rule 8 (6th dot point) and Rule 9 (4th paragraph):

The device is classified as Class III if it is:

(1) An active implantable medical device.

(2) An accessory to an active implantable medical device.

(3) An active medical device that is intended by the manufacturer to be used to control or monitor, or directly influence, the performance of an active implantable medical device.

(4) Software that drives an active implantable medical device or influences the use of such a device.

What will change for sponsors?

If the regulatory changes take effect, sponsors of ***AIMD*** and ***non-implantable accessories to AIMD*** will be required to apply for inclusion of their medical devices in the ARTG as Class III.

[15] *Therapeutic Goods (Medical Devices) Regulations 2002*, r.3.6 and Schedule 3 – Conformity assessment procedures

[16] *Therapeutic Goods Act 1989*, s.3

Sponsors who supply or plan to supply medical devices that are not currently classified as high-risk devices (i.e. non-implantable accessories) in Australia will be required to provide manufacturer's *conformity assessment documents* appropriate to devices of high-risk classification.[17]

Transitional arrangements

In Europe, under the transitional arrangements, medical devices lawfully placed on the market that have pre-market authorisation in the form of a valid EC Certificate[18] can remain on the market until the expiry date of that EC Certificate or until 27 May 2024 (when these certificates become void), whichever is the earliest. Devices lawfully placed on the market may continue to be made available on the market or put into service until 27 May 2025.

The TGA proposes that the new classification for **new medical devices in Australia**—that is, a device included in the ARTG following successful completion of applications submitted to the TGA on or after the commencement date of the amended regulations—would start from August 2020.

If the application for ARTG inclusion for a medical device is **submitted to the TGA before the date the proposed amendment takes effect**, it is proposed that the **device will be subject to the transitional arrangements** and will have four (4) years to transition until August 2024.

Applications

At the date that the proposed amendments take effect:

- **All new applications for marketing approval** (ARTG inclusion) for active implantable medical devices and any of their accessories (including non-implantable devices) submitted to the TGA on or after the date when amended regulations take effect must be for a Class III medical device.

  Sponsors of devices already included in the ARTG that are not Class III currently, or those for which applications have been submitted before regulatory amendments take effect, must apply to have their device/s re-entered as Class III medical devices. All applications to reclassify devices must be submitted to the TGA by the end of the four year transition period. Where an application to reclassify has been submitted to the TGA but has not been determined (i.e. is still under assessment), the device can continue to be supplied under the existing ARTG entry until the Class III application is finalised (including applications not finalised at the end of the transition period).

- The **requirement to select any Class III ARTG inclusion application** for medical devices, for which TGA has not issued a conformity assessment certificate **for audit, will not apply** to **applications for changing the classification of AIMD to Class III**.

- For those devices for which transitional provisions apply, sponsors must notify the TGA of all such devices presently supplied under the existing ARTG entry within six (6) months of the amended regulations taking effect (i.e. by February 2021). These devices can continue to be supplied for the duration of the four year transition. If the sponsor has not notified the TGA within this period, they will no longer be eligible for the transitional arrangements.

[17] Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion) Determination 2018 (F2018L01410) <https://www.legislation.gov.au/Details/F2018L01410>

[18] EC certificates issued in accordance with EU Directive 93/42/EEC and which comply with the requirements in para. (2) of Article 120 of the EU MD Regulation.

- If any **application for ARTG inclusion for a device with the current classification is in progress** on the date the regulations come into effect, it may continue. If the application is successful, the device will be included with the current classification (i.e. for which the application was made). The sponsor must then reapply to include their device in ARTG as Class III, as per requirements set out under the transitional arrangements.

Fees and charges

The usual application fee will apply for applications for inclusion of a medical device in the ARTG.

Applications **for changing the classification of AIMD to Class III** will be excluded from the requirement to pay audit assessment fee.

The usual annual charges will apply for any Class III entries in the ARTG following reclassification.

Engagement

Wherever practicable, the TGA will:

- Liaise with the healthcare sector, patient associations and industry peak bodies to inform and raise awareness about this proposal
- Provide relevant material on the TGA website.

Feedback notes

It is important to note that while we intend to take the European medical device framework into account the Australian legislative instruments are structured differently and there is variation in the legal terminology acceptable in each jurisdiction. We acknowledge that legislation cannot always be successfully replicated across jurisdictions. Therefore, your views on the impacts of changing classification of active implantable medical devices and reclassifying their accessories to Class III are very important to us.

When considering the proposed measures, assume that the EU MD Regulation definitions and terminology and the sixth dot point of Rules 8 and fourth paragraph of Rule 9 apply to active implantable medical devices and their accessories in the context of the Australian MD Regulations. You also may wish to consider the possible impact of the proposed alignment by referring to descriptions of relevant devices and their functionality.

Please also keep in mind that current and future technological developments may potentially bring more categories of medical devices under these classification rules.

What we invite you to do

In your submission, we ask you to consider the questions below and provide comments related to any other matter outlined in this consultation paper.

Questions

- What impacts—including any that are unintended—do you anticipate the proposed amendments may have for yourself and other stakeholders (such as consumers, healthcare professionals, health organisations, industry etc.)?
- Are there any further issues and questions we should consider when implementing this change (including areas that can/should be clarified in our guidance)?
- Do you have any comments/views regarding all or some of non-implantable accessories to AIMD that are proposed to be reclassified to Class III? Is reclassification of these devices in Australia to Class III appropriate?
- Do you have any comments regarding the transitional arrangements proposed in this paper?

How to submit

Complete the online consultation submission form to upload your submission in either pdf or word format.

You can also submit your feedback directly to the TGA by email at: devicereforms@tga.gov.au. If you do so, **please ensure your submission is accompanied by a coversheet**.

This consultation closes on 29 April 2019.

Enquiries

If you have any questions relating to submissions please direct them to: devicereforms@tga.gov.au.

Appendix A – Classification Rules and Definitions

Table A below is a comparison of current classification rules, definitions and other provisions by jurisdiction.

Table A – Regulatory provisions relevant to active implantable medical devices and other devices used together with AIMD

Australian MD Regulations	EU MD Regulation	Difference / Proposed amendments
	Introductory part, p.2 (6) For historical reasons, active implantable medical devices, covered by Directive 90/385/EEC, and other medical devices, covered by Directive 93/42/EEC, were regulated in two separate legal instruments. In the interest of simplification, both directives, which have been amended several times, should be replaced by a single legislative act applicable to all medical devices other than *in vitro* diagnostic medical devices.	N/A
	p. 8 (58) It is necessary, in particular for the purpose of the conformity assessment procedures, to maintain the division of devices into four product classes in line with international practice. The classification rules, which are based on the vulnerability of the human body, should take into account the potential risks associated with the technical design and manufacture of the devices. To maintain the same level of safety as provided by Directive 90/385/EEC, active implantable devices should be in the highest risk class.	N/A

Australian MD Regulations	EU MD Regulation	Difference / Proposed amendments
Dictionary (regulation 1.3) ***Active implantable medical device*** or ***AIMD*** means an active medical device, other than an implantable medical device, that is intended by the manufacturer: (a) either (i) to be, by surgical or medical intervention, introduced wholly, or partially, into the body of a human being; or (ii) to be, by medical intervention, introduced into a natural orifice in the body of a human being; and (iii) to remain in place after the procedure	The EU MD Regulation does not explicitly define *active implantable medical devices.*	The Australian MD Regulations provide a specific definition of *active implantable medical device* (AIMD), whilst the EU MD Regulation does not provide an explicit definition. Therefore, the Australian MD Regulations provide greater clarity compared with the EU MD Regulation. Accordingly, it is not proposed to amend the Australian definition of *active implantable medical device* (AIMD). **No change is proposed.**
The Australian MD Regulations do not provide specific interpretation of software as a medical device nor is there a specific classification rule pertaining to software as a medical device.	**ANNEX VIII** **CHAPTER II IMPLEMENTING RULES** 3.3 Software, which drives a device or influence the use of a device, shall fall within the same class as the device.	TGA is consulting separately on the regulatory requirements for software as a medical device. For the purposes of this consultation, software, that drives an active implantable medical device or influence the use of such device is classified as Class III medical device. **It is proposed that the same principle for applying the classification rules should be included in the Australian MD Regulations.**

Australian MD Regulations	EU MD Regulation	Difference / Proposed amendments
Schedule 2—Classification rules for medical devices other than IVD medical devices **Part 5—Special rules for particular kinds of medical devices** **5.7 Active implantable medical devices** (1) An active implantable medical device is classified as Class AIMD. (2) An implantable accessory to an active implantable medical device is classified as Class III.	**ANNEX VIII** **CHAPTER III CLASSIFICATION RULES** **5. INVASIVE DEVICES** **5.4 Rule 8** All implantable devices and long-term surgically invasive devices are classified as class IIb unless they: […] *(6th dot point)* • are active implantable devices or their accessories, in which cases they are classified as class III;	TGA is consulting on the definition of ***accessory*** to a medical device separately[19]. The Australian MD Regulations currently provide that only **implantable medical device-accessories** associated with the use of AIMD are Class III, whilst all other -accessories (i.e. non-implantable) are of the lower classification. The EU MD Regulation classifies **all medical device-accessories** associated with the use of an AIMD as high-risk (Class III). **It is proposed** that the Australian MD Regulations be amended to reflect high-risks associated with the use of AIMD and their accessories, i.e. that **all accessories to AIMD** are Class III devices.
(3) An active medical device that is intended by the manufacturer to be used to control or monitor, or directly influence, the performance of an active implantable medical device is classified as Class III.	**ANNEX VIII** **CHAPTER III CLASSIFICATION RULES** **6. ACTIVE DEVICES** **6.1. Rule 9** […] *(4th paragraph)* All active devices that are intended for controlling,	The intent of the EU Rule 9 (4th paragraph) is consistent with the intent of the Australian Rule 5.7(3). It is proposed that slight drafting differences in these rules will be reviewed for clarity purposes.

[19] See Consultation: Changes to a number of definitions and scope of the medical device regulatory framework in Australia, Appendix A, Table A1, p.13

Australian MD Regulations	EU MD Regulation	Difference / Proposed amendments
	monitoring or directly influencing the performance of active implantable devices are classified as class III.	**No other changes are proposed.**

Appendix B – Examples

Table B – Some examples of AIMD and devices used together with AIMD, and their current classification

Device	Australian MD Regulations	
	Current rules	Proposed classification
B.1 – Implantable cardiac pacemakers		
The pacemaker's **pulse generator** is a small pulse-generating implantable battery-powered device that is implanted in the chest or abdomen under the skin. It emits electrical impulses through leads to the heart. Some pacemakers operate without the use of wired leads, with the pulse generator implanted directly in the chamber of the heart. The rate at which the electrical impulses are sent out is called the pacing rate. The pulse generator is intended to restore or establish a normal heart beat when the heart beats too fast, too slow or at an irregular rhythm.	5.7(1) – **AIMD**	**Class III**
Pacemaker leads are flexible insulated wires that connect the pulse generator to the heart. A lead detects the heart rhythm and transmits this information to the pulse generator, which responds in a way that is appropriate to that rhythm. Although they are designed to be implanted permanently in the body, occasionally these leads must be removed or extracted. The most common reason for lead extracted is device infection.	5.7(2) – implantable accessory – Class III	No change
Pacemaker programmer is an external computer and associated software designed especially to communicate with the pulse generator, and for doctors to download the information stored in the pacemaker and adjust it to the patient's particular needs if necessary.	5.7(3) – active devices intended for controlling, monitoring or directly influencing performance of AIMD – Class III	No change
Pacemaker system analyser contains a non-implantable magnetic test device to be placed outside the patient in the area close to the implanted pacemaker. The magnet will activate the magnet sensitive relay in the pacemaker and will change the function of the pacemaker. Device can include software that reads information about the condition of the pacemaker, and transfer the information via an electrocardiograph machine.	**Various** depending on the composition of the device	**Class III**

Device	Australian MD Regulations	
	Current rules	Proposed classification
Intracardiac pacemaker programming interface unit is an external, electronic device intended to interface a dedicated patient lead with a pacemaker programmer (from which it draws its power), to enable non-invasive interrogation and programming of an implanted intracardiac pacemaker using high frequency electrical pulses (as an alternative to wireless communication). It is also intended to collect electrocardiogram (ECG) data for observation of pacemaker function. Pacemaker communication and ECG data collection is achieved via the patient cable/electrodes which are typically included. The device is intended to be used by a healthcare professional in a clinical setting.	5.7(3) – active devices intended for controlling, monitoring or directly influencing performance of AIMD – Class III	No change
Pacemaker repair kit contains the necessary tools and materials for the repair or replacement of an implantable pacemaker. Typical components include tools, adhesive, sealant, screws, crimps, or any other tools/materials used to repair a pacemaker lead or to reconnect a pacemaker lead to a pacemaker.	**Various** depending on the composition of the device	**Class III**
Implantable pacemaker bag is an implanted device used to hold a pacemaker. The bag is designed to create a stable implant environment for the pacemaker. This device is typically constructed from polymeric mesh.	5.7(2) – implantable accessory – Class III	No change
Pacemaker/defibrillator port safety plug is a device used to seal the unused connector port of an implanted pacemaker or an ICD to provide electrical isolation and protect the parent device from the extremely hostile environment of the human body when implanted. It is typically made of high-grade stainless steel and silicone and will be inserted sterile into the vacant port (e.g. an IS-1 connection).	5.7(2) – implantable accessory – Class III	No change
Pacemaker/defibrillator lead extraction kit contains instruments designed to remove implanted pacemaker or defibrillator leads. The instruments contained within the kit are typically used in combination to extract the implanted lead. Typical kit components include stylets, dilating sheaths, snares, and retrieval baskets.	**Various** depending on the composition of the device	**Class III**
Pacing lead cap is a device that is used to cover and protect the lead terminals of an implantable pacing device (e.g. an implanted pacemaker/defibrillator) during the implantation procedure or to isolate (cap) any lead	5.7(2) – implantable accessory – Class III	No change

Device	Australian MD Regulations	
	Current rules	Proposed classification
terminals that are not used. This device is implanted along with the pacemaker/defibrillator system.		
Implantable pacemaker battery is a sterile, hermetically-sealed, implantable, electrochemical cell designed to store chemical energy and release it in the form of electrical power to operate a co-implanted pacing device (e.g. pacemaker, wireless pacemaker sensor/transmitter).	5.7(2) – implantable accessory – Class III	No change
Interface software is designed to present information in a reader-friendly way. This software program may be permanently installed or exchanged as an upgrade.	**Various** depending on a specific intended purpose	**Class III**
Pacemaker battery charger is an electronic device intended to be used to wirelessly recharge the batteries of an active implantable device in situ. It is not intended to program or extract data from (read) the implanted device.	5.7(3) – active devices intended for controlling, monitoring or directly influencing performance of AIMD – Class III	No change
B.2 – Implantable cardioverter-defibrillator		
The **defibrillator** is a device intended to continuously monitor the heart and automatically deliver therapies to correct fast heart rhythms when necessary.	5.7(1) – **AIMD**	**Class III**
The **leads** are thin, soft insulated wires that carry the electrical impulse from the defibrillator to the heart and relay information about the heart's natural activity back to the defibrillator.	5.7(2) – implantable accessory – Class III	No change
An **ICD programmer** is a computer with the associated software, that are used outside the body to display the battery voltage, the ICD settings and any rhythm disturbances that have been detected, and any therapy that has been delivered since the last time the data was displayed.	5.7(3) – active devices intended for controlling, monitoring or directly influencing performance of AIMD – Class III	No change
ICD battery is a device that usually lasts between four and eight years, depending on how many shocks it delivers. When the battery runs down, a new ICD needs to be implanted.	5.7(2) – implantable accessory – Class III	No change

Device	Australian MD Regulations	
	Current rules	Proposed classification
Implantable defibrillator analyser is a device used to assess and/or monitor the performance of an automatic implantable cardioverter-defibrillator (AICD) system at the time of implantation or in the electrophysiology (EP) laboratory. This device typically monitors the electrographic signals from the implanted electrode/leads, provides information on the patient's defibrillation/cardioversion energy threshold, and monitors and/or records electric cardiac signals during arrhythmia induction. It typically consists of an electronic unit including a display, measuring modes (energy, voltage, time), and a pulse generator.	5.7(3) – active devices intended for controlling, monitoring or directly influencing performance of AIMD – Class III	No change
Cardiac pulse generator software is an application or operating data program (i.e. primarily operating system software that may include some application program functionality) designed for use in or with an ICD so that it can function according to its intended purpose. This software program may be permanently installed or exchanged as an upgrade.	5.7(3) – active devices intended for controlling, monitoring or directly influencing performance of AIMD – Class III	No change
ICD repair kit contains the necessary tools and materials for the repair or replacement of an ICD. Typical components include tools, adhesive, sealant, screws, crimps, or any other tools/materials used to repair a lead or to reconnect a defibrillator lead to a defibrillator.	**Various** depending on the composition of the device	**Class III**
B.3 – Cochlear implants		
The **processing unit** (the outside component) is a medical device that is generally worn behind the ear. In young children, it can be attached to clothing. This component has a microphone (picks up sound from the environment), a speech processor (selects and arranges sounds picked up by the microphone) and a transmitter and receiver/stimulator (receive signals from the speech processor and convert them into electric impulses).	5.7(3) – active devices intended for controlling, monitoring or directly influencing performance of AIMD – Class III	No change
The **cochlear implant** (the inside component)is a device containing coil (sits over the implant) designed to receive signals, a coil cable, electronics and an array of electrodes that are placed into the cochlea that stimulate the cochlear nerve.	5.7(1) – **AIMD**	**Class III**

Device	Australian MD Regulations	
	Current rules	Proposed classification
Cochlear implant system battery pack is a non-sterile external portion of a cochlear implant system that typically consists of a holder or container holding batteries that supply direct current to all of the electrically-powered/dependent components of the cochlear implant. It is typically worn behind-the-ear and may include an on/off switch.	5.7(3) – active devices intended for controlling, monitoring or directly influencing performance of AIMD – **Class III**	No change
Cochlear implant system connector is a device designed to be used with a cochlear implant system to connect the sound processor to power options, e.g. battery pack, and/or to enable connections to external devices that may be used as peripherals to the implant system.	2.1 – Non-invasive medical device – **Class I**	**Class III**
Cochlear implant system external magnet is a small, non-sterile, magnetic device intended to hold in place a cochlear implant system coil on the outside of the scalp, typically by coupling with an implanted magnet. It is typically a magnetized metal disc that is attached to the coil, but may be supplied separately.	2.1 – Non-invasive medical device – **Class I**	**Class III**
Cochlear implant system sound processor ear hook is a small hook-shaped or formable device designed to be attached to a cochlear implant sound processor to facilitate wearing behind the ear. It is typically made of synthetic polymer materials.	2.1 – Non-invasive medical device – **Class I**	**Class III**
Cochlear implant system waterproof kit is a collection of non-sterile devices intended to be used with a cochlear implant system to protect the externally worn components in wet and/or rugged environments (e.g. for swimming, showering). The set typically consists of a sound processor case, waterproof microphone, and a connection cable.	2.1 – Non-invasive medical device – **Class I**	**Class III**
Cochlear implant system evaluation application software is an individual software application program or group of programs intended to conduct analysis of cochlear implant functionality *in situ*. It is intended to be installed in an off-the-shelf desktop or laptop computer and uses the implanted cochlear implant and a sound processor to trigger stimulation and measure the voltage results. It is typically used in medical facilities and operated by specialised clinical support technicians. Applications program packages are typically identified by a proprietary name and "version" or "upgrade" number.	5.7(3) – active devices intended for controlling, monitoring or directly influencing performance of AIMD – Class III	No change

Device	Australian MD Regulations	
	Current rules	Proposed classification
Stimulator, electrical, auditory, cochlea is a device intended for the partial restoration of auditory sensation to profoundly deaf persons. This device consists of an electrode array that is surgically inserted in one cochlea, a receiver-stimulator that is implanted in the skull near the ear, and a speech processor that is worn externally which converts sound into electrical signals to be transmitted to the receiver-stimulator.	5.7(1) – **AIMD**	**Class III**
Remote control, cordless is a cordless (wireless) control panel/unit used to control/activate other medical devices or equipment from a distance (remotely). This device is typically hand-held.	5.7(3) – active devices intended for controlling, monitoring or directly influencing performance of AIMD – Class III	No change
Cochlear implant system coil is the non-sterile external portion of a cochlear implant system that typically consists of a battery-powered, behind-the-ear transmitter designed to transmit direct current and stimulation data (electrical signals) to the implantable receiver-stimulator and electrode array assembly of the cochlear implant for the partial restoration of auditory sensation in a profoundly deaf person. It is a round-shaped device approximately 30 mm in diameter with a magnet in its centre to magnetically couple with the internal receiver-stimulator; it connects to the sound processor via a cable.	**Various** depending on a composition of the device and specific intended purpose	**Class III**

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Therapeutic Goods Administration, Medical Devices Branch	March 2019

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